

REMARKS

The Applicant acknowledges the receipt of the message 12/23/03 informing the Applicant that new art would be applied to the claims and the finality withdrawn.

In the Office Action, the Examiner rejected claims 78-80, 85-87 and 89-91 under 35 USC 102 and claims 36, 41-46, 53, 57, 66, 67, 76, 81, 100-104 under USC 103. These rejections are fully traversed below.

Claims 36, 37, 41, 45, 51, 57, 78 and 79 have been amended. Claims 105-110 have been added. Claims 48-50, 52, 54-56, 58-65, 68-75, 77, 87 and 92-99 have been withdrawn. Thus, claims 36-39, 41-46, 48 87, 89-99 and 100-110 are pending in the application. Reconsideration of the application is respectfully requested based on the following remarks.

Claim Rejections – 35 USC § 102

Claims 78-80, 85-87 and 89-91 have been rejected under 35 U.S.C. 102(e) as being anticipated by *Gough* et al. (USPN 5,863,290).

In contrast to *Gough*, claim 78 (and its dependents) specifically requires, "...the shape of the elongated energy portion following the contour of an inner wall of a heart when in the deployed state so that the elongated energy portion substantially conforms to the inner wall of the heart when the elongated shaft is positioned through a penetration in the wall of the heart..." While *Gough* may disclose secondary electrode 16 made of shape memory metals such as NiTi, *Gough* does not teach or suggest an antenna 16 that has a shape that follows the contour of the heart. First, *Gough* is completely silent to hearts. Second, *Gough* makes no mention of organ shapes. Moreover, *Gough* is directed at creating ablation volumes and thus there would be no need to follow the contour of an organ. Accordingly, the rejection is unsupported by the art and should be withdrawn.

Although the rejections to the dependent claims 79, 80, 85-87 and 89-91 should be withdrawn for at least the reasons as above, it should be noted that they offer additional language that is unsupported by the art. For example, claim 80 specifically requires, "wherein the energy

delivery portion further comprises a conductive layer overlying the shape memory material.” No such limitation is disclosed in *Gough* and thus the 102 rejection should be withdrawn.

In the outstanding office action, the Examiner stated in reference to Col. 5, lines 23-45 and Figures 1-8, that *Gough* disclosed a dielectric layer 18 that encapsulates the antenna 16. This however is incorrect. Neither the description or the Figures show an encapsulated antenna, but rather sleeve 18 that only covers a portion of the antenna 16. In fact, *Gough* teaches away from encapsulation in the referenced description. For example, *Gough* states that each insulation sleeve 18 is adjustably positioned so that the length of an antenna ablation surface can be varied (Col. 5, lines 25-28). Furthermore, all of the Figures show the sleeve 18 only covering a proximal section of the antenna 16 leaving the remainder exposed and not encapsulated.

Claim Rejections – 35 USC § 103

Claims 36, 41-46, 53, 57, 66, 67, 76 and 100-104 have been rejected under 35 USC 103(a) as being unpatentable over *Gough et al.* in view of *Kasevich* (USPN 6,233,490).

Independent Claim 36

In contrast to both references, claim 36 specifically requires, “wherein upon deployment the antenna device is straight and assumes an angular orientation relative to a longitudinal axis of the introducer, the angular orientation placing the straight antenna device in a direction towards and substantially parallel to an interior portion of the penetrated wall in order to allow a linear lesion to be produced at the tissue region of the penetrated wall which is targeted for ablation.” *Kasevich* is silent to deploying the antenna array 12 out a penetration end of an introducer. And while *Gough* may disclose deploying a secondary antenna 16 out of an aperture formed in the primary antenna 14, *Gough* does not teach or suggest a deployed antenna that is straight, or one that assumes an angular orientation that places the antenna in a direction towards and substantially parallel to an interior portion of the penetrated wall in order to allow a linear lesion to be produced at the tissue region of the penetrated wall which is targeted for ablation. The secondary antennas of *Gough* are bent or curved and thus they are not straight (see the various figures of *Gough* in addition to Col. 4, lines 65-67, which discusses the deflection of the antenna). Furthermore, the curved antenna simply cannot be parallel with a surface, i.e., there

would be portions of the antenna farther from the surface than others (e.g., non parallel). See for example Fig. 1 of *Gough*. Moreover, the curved antennas would make it difficult to form linear lesions. It should be emphasized that the antennas of *Gough* are used to form ablation volumes rather than linear lesions (See for example Figs. 2, 4 and 5 and Col. 2, lines 43-45). Accordingly, the rejection is unsupported by the art and should be withdrawn.

Also in contrast to both *Gough* and *Kasevich*, claim 36 (and its dependents) specifically requires, "...the antenna device including an antenna that is coupled to a distal end of the inner conductor of the coaxial transmission line" While both references may disclose "microwave antennas" and *Kasevich* may disclose coaxial transmission lines, neither of the references teach or suggest a microwave antenna that is coupled to an inner conductor of a coaxial transmission line. Accordingly, the rejection is unsupported by the art and should be withdrawn.

Also in contrast to *Gough*, claim 36 specifically requires "an enclosure that encapsulates the antenna with a dielectric material." As stated above, *Gough* does not teach or suggest encapsulation. *Gough* teaches primary and secondary antennas that have exposed ablation delivery surfaces. That is, both the primary and secondary antenna 14 and 16 are exposed conductors that have exterior ablation surfaces. (see col. 5, lines 3-9 and lines 38-39). If these were encapsulated, they would no longer be ablation surfaces and therefore they may not work as intended. In fact, *Gough* may be teaching away from full encapsulation when he states that insulation sleeve 18 is positioned so that the length of the ablation surface can be varied (See Col. 5, lines 23-31). Based on this, it is also believed that *Gough* and *Kasevich* cannot be properly combined. Accordingly, the rejection is unsupported by the art and should be withdrawn.

Independent Claim 57

In contrast to both references, claim 57 (and its dependents) specifically requires, "...a probe configured to penetrate the wall of the beating heart...said probe being configured to penetrate the wall of the beating heart to facilitate placement of the microwave energy delivery portion within an interior cavity of the beating heart, the microwave energy portion being configured to be deployed from the probe when placed within the interior cavity of the beating heart..." Both *Gough* and *Kasevich* are completely silent to devices capable of penetrating walls

of beating hearts as well as devices capable of ablating portions of beating hearts. Thus, the rejection is unsupported by the art and should be withdrawn.

Also in contrast to both references, claim 57 (and its dependents) specifically requires, "...the microwave energy portion also being configured the match the shape of the interior portion of the wall and to linearly ablate the interior portion of the wall of the beating heart when deployed within the interior cavity of the beating heart..." *Kasevich* is silent to deploying microwave energy portion. And while *Gough* may disclose a secondary antenna, *Gough* does not teach or suggest a secondary antenna that matches the shape of the interior portion of an organ or duct let alone a beating heart. *Gough* is also silent to forming linear lesions (e.g., linearly ablate). In *Gough*, the antennas are used to form an ablation volume not linear lesions. This in of itself would make it difficult to form linear lesions. Accordingly, the rejection is unsupported by the art and should be withdrawn.

Independent Claim 76

In contrast to both references, claim 76 (and its dependents) specifically requires, "...the antenna device and a portion of the outer conductor of the coaxial transmission line being deployed beyond the distal penetration end of the elongated shaft when the distal penetration end of the elongated shaft is positioned within the organ or duct..." As shown in Fig. 3B of the present invention, the outer conductor 32 is arranged to have a distal portion 39 that is exposed beyond the penetration end 16 of the probe when the antenna device is in its advanced position. And as stated in the specification of the present invention on page 20, lines 8-11, "...it is generally believed that the radiated field tends to be more confined along the antenna device 30 when the distal end of the outer conductor 32 is extended in the organ cavity and exposed to the surrounding medium." No such arrangement is shown or described in *Gough* or *Kasevich*. *Gough* is silent to coaxial transmission lines and thus outer conductors that are deployed past the distal end of the primary antenna 14. In fact, one may say that *Gough* teaches away from this approach via insulation sleeve 18. As shown in Fig. 1, insulation sleeve 18 is positioned around secondary antenna 16 at the distal end 14' of primary antenna 14. *Kasevich* does not overcome these deficiencies. In particular, *Kasevich* is silent to deploying an antenna device or any portion of a coaxial transmission line out of an elongated shaft. Accordingly, the rejection is unsupported by the art and should be withdrawn.

Independent Claim 100

In contrast to both references, claim 100 (and its dependents) specifically requires, "...the longitudinal energy delivery member being configured to conform to an inner wall of the organ when deployed inside the cavity of the organ so as to produce a substantially linear lesion on the inner wall of the organ when energy is delivered to the longitudinal energy delivery member." *Kasevich* is silent to deploying an energy delivery member. And while *Gough* may disclose a secondary antenna, *Gough* does not teach or suggest a secondary antenna that conforms to an inner wall of the organ or that produces a linear lesion. *Gough* is directed at devices that are inserted into a body mass such as a tumor, and thus there is no wall to conform to. *Gough* is also silent to forming linear lesions (e.g., linearly ablate). In *Gough*, the antennas are used to form an ablation volume not linear lesions. Accordingly, the rejection is unsupported by the art and should be withdrawn.

Although the rejections to the dependent claims 41-46, 53, 66, 67 and 101-104 should be withdrawn for at least the reasons as above, it should be noted that they offer additional language that is unsupported by the art. For example, claim 102 specifically requires, "an antenna that is encapsulated by a dielectric medium." As stated above, *Gough* does not teach or suggest encapsulation. Accordingly, the rejection is unsupported by the art and should be withdrawn.

Claim 81 has been rejected under 35 USC 103(a) as being unpatentable over *Gough et al.* in view of *Laird et al.* (USPN 6,533,780).

While *Laird* may disclose coating electrode tubes with a biocompatible material such as silver, *Laird* does not teach or suggest coating a shape memory material as required in the claims. *Laird* only mentions coating stainless steel, brass, copper, steel, titanium and gold. No mention is made to shape memory materials. As stated in the specification of the present invention, "the antenna wire can be formed from a shape memory metal such as NiTi (Nitinol)...the electrical conductivity of Nitinol is not very good, and as a result Nitinol can heat significantly when power is applied. In one implementation therefore a layer of good conducting material is disposed over Nitinol. For example, silver plating or deposition may be used (page 18, 1st paragraph)." Accordingly, the rejection is unsupported by the art and should be withdrawn.

Claim 51 has been rejected under 35 USC 103(a) as being unpatentable over *Gough et al.* in view of *Kasevich* as applied to claim 36 above, and further in view of *Guziak et al.* (USPN 6,162,216).

Guziak does not overcome the deficiencies of *Gough* and *Kasevich*. None of these references teach or suggest “wherein upon deployment the antenna device is straight and assumes an angular orientation relative to a longitudinal axis of the introducer, the angular orientation placing the straight antenna device in a direction towards and substantially parallel to an interior portion of the penetrated wall in order to allow a linear lesion to be produced at the tissue region of the penetrated wall which is targeted for ablation,” as required by claim 36 from which claim 51 depends.

In any event, claim 51 specifically requires, “wherein an outer diameter of the introducer is less than about 3 mm.” As stated in the specification of the present invention on page 13, 2nd full paragraph, “This relatively small diameter size is particularly suitable for use in highly vascularized organs such as the heart so as to minimize the puncture diameter and thus potential bleeding.” It appears that *Gough* and *Kasevich* give no indication of size. This may be because *Gough* and *Kasevich* are not directed at treating the heart, but rather tumors and therefore size may not matter as much. It therefore wouldn’t be obvious to one skilled in the art to combine them with *Guziak*. That is, there is no motivation to combine. Accordingly, the rejection is unsupported by the art and should be withdrawn.

Allowable Subject Matter

Allowed claim 37 was amended to include the limitations from independent claim 36. Claim 37 (and its dependents 38 and 39) are therefore allowable as the Examiner indicated allowable subject matter in the previous Action.

Summary

Applicant believes that all pending claims are allowable and respectfully requests a Notice of Allowance for this application from the Examiner. Should the Examiner believe that a telephone conference would expedite the prosecution of this application, the undersigned can be reached at the telephone number set out below.

Respectfully submitted,
BEYER WEAVER & THOMAS, LLP

A handwritten signature in black ink, appearing to read "Hoellwarth", with a stylized flourish at the end.

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